# Exhibit 4

96.433-80

PROPERTY OF ADVANCED CARDIOVASCULAR SYSTEMS, INC.



Advanced Cardiovascular Systems, Inc.

3200 Lakeside Drive P.O. Box 58167

Santa Clara, CA 95052-8167

HANB Larry Wasicek

1260 LAB. NOTEBOOK NO. 126 ISSUE DATE 1/25/94

RETURN DATE 9/20/96

RETURN TO DOCUMENT CONTROL FOR ARCHIVING.

PEEK Post Process Evaluation 15/3/4 TITLE:

To determine the post extrusion process conditions for different **OBJECTIVE:** 

extrusion runs. Five of the extrusions were completed at ACS and

one extrusion at Accutech.

#### MATERIALS:

Description	Part Number	Source	Conditions/Comments
PEEK	EXTR.# 10-552-1	in-house	Water bath was 8 degrees (c)
PEEK	EXTR.# 10-554-1	in-house	Was air cooled extrusion
PEEK	EXTR.# 10-553-1	in-house	Water bath was 70 degrees (c)
PEEK	EXTR.# 10-543	in-house	
PEEK	EXTR.# 581	in-house	

Notes:

PEEK

Runs number 543 and 581 have similar extrusion run conditions.

AP0001842

**PROCEDURES:** 

Place a .031" Teflon mandrel inside the PEEK and with a hot box set at Necking:

475 degrees (f) try to neck the material. Necking is done at the end of the

Teflon mandrel while tension is applies where there is no mandrel.

outside vendor

Use a .042" ID TFE sheath and hot box set at 500 (f) with 110 psi and

expand.

#### Rating Matrix

Part Number	Expanding	Necking	Surface Terrible Bumps Good Terrible Bumps Very Good
EXTR.# 10-552-1	N/A	N/A	
EXTR.# 10-543	Good	Good	
EXTR.# 10-554-1	Good	Good	
EXTR.# 10-553-1	Good	Good	
EXTR.# 581	Good	Good	
AP0001842	Good	*OK	very Good

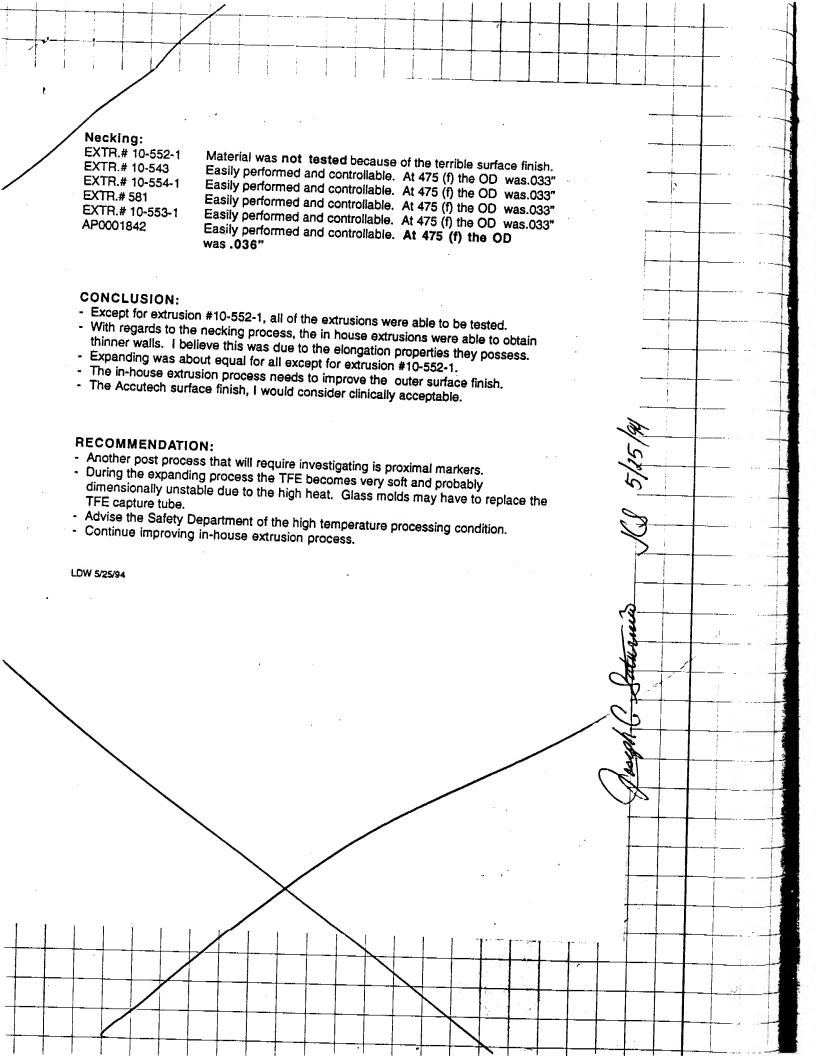
<sup>\*</sup> See dimensions below

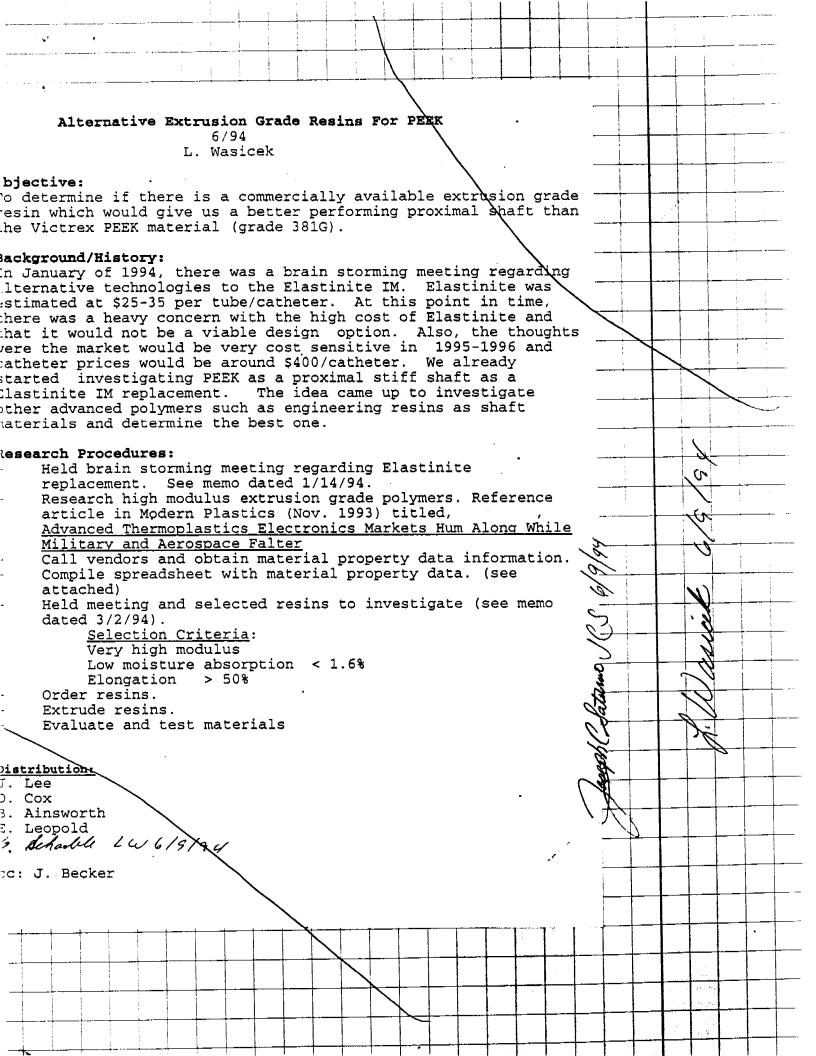
Expanding Comments:

Material was not tested because of the terrible surface finish. EXTR.# 10-552-1

Easily performed and controllable. EXTR.# 10-543 Easily performed and controllable. EXTR.# 10-554-1 Easily performed and controllable. EXTR.# 581 Easily performed and controllable. EXTR.# 10-553-1 Easily performed and controllable. AP0001842

Distribution: B. Ainsworth, D. Cox, E. Leopold, S. Schaible, J. Lee, E. Williams, R.Cherry





### Materials: Extrusion Run Numbers: High Temperature Engineering Resins: Polyetheretherketone (PEEK) Acutech (outside vendor) Polyethersulfone (PES) #10-576-1 Polyphenylenesulfide (PPS) #10-556 Polyaryletherketone (PAEK) N/A Other Resins Included In The Analysis: EVAL 12-142 Pebax 7233 11-223 Nylon 12 11-221 Isoplast 10-531-1 \*Hytrel N/APET 11-219-1 \*Note: Hytrel was extruded but testing was stopped due to vendor agreement problems. Tests: Tinius Olson Slope: This is the slope using angles 0,3,6,9. Tinius Olson Kink: Record the peak load value before it kinks and looses it's strength. Circle Kink: Put the tubing in a circle and continue to decrease the circle size while matching it to a circle template. Record the smallest circle the material would fit before kinking. This test should be used for reference only: Rupture pressure: Record the average rupture pressure. Mechanical: Modulus, elongation, and strength. Testing completed at ACS at room temperature. Acceptance Criteria: Tinius Olson Slope: Catheter having the highest number is considered the best. Tinius Kink: Catheter having the highest number is considered the Circle Kink: Reference information only. Rupture Pressure: Catheter must be able to withstand a minimum of 350 psi. (Protocol located in E. Williams lab notebook) Modulus & Strength: Having a high modulus & strength is considered having better stiffness for the shaft performance. Elongation: This material property is best correlated with post processing operations. For now, tubing should have a minimum elangation of at least 50%. This number is based on the post processing conditions from prior experiments using in-house and Accutech PEEK extrusions. Results: See attached spreadsheets.

## onclusion: Material Summary - Compared to PEEK: EEK: This material has the highest modulus (408-428kpsi), strength (15.3-16.2 kpsi), Tinius Olson slope (4.28) & kink angle (79 degrees). It also has a rupture pressure over 500psi with an elongation of 56-69%. In my opinion this is the best material of all the materials tested. ΞS Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 323kpsi). Tinus Olson slope is 2.21 compared to PEEK at 4.27 and the T/O kink angle is 45 degrees compared to PEEK's 79 degrees. material has adequate rupture pressure at 500psi, plenty of elongation at 150%. It has a strength value of 15,200 psi compared to PEEK 15,300 - 16,200 psi. PS: Compared to PEEK this material does not have as high a modulus (408-428kpsi vs 297 kpsi). Tinus Olson slope is 2.63 compared to PEEK at 4.27 and the T/O kink angle is 44 degrees compared to PEEK's 79 degrees. Rupture pressure is OK at 411 psi. Elongation at 335% is acceptable. It has a strength value of 10,700 psi compared to PEEK 15,300-16,200 psi. ebax: This material has a poor Tinius Olson slope of .71 and a T/O kink angle of 17 degrees. The modulus was approximately 1/4 that of PEEK at 104 kpsi. Rupture pressure was adequate at 411 psi along with an elongation of 285%. It's strength compared to PEEK is 10,900 psi vs 15,300-16,200 soplast: Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 314 kpsi). Tinus Olson slope is 3.01 compared to PEEK at 4.27 and the T/O kink angle is 59 degrees compared to PEEK's 79 degrees. Rupture pressure is OK at 387 psi. Elongation at 130% is acceptable. It has a strength value of 13,900 psi compared to PEEK 15,300 - 16,200 psi.

PET: Compared to PEEK this material does not have as high a modulus (408-428 kpsi vs 311 kpsi). Tinus Olson slope is 1.76 compared to PEEK at 4.27 and the T/O kink angle is 31 degrees compared to PEEK's 79 degrees. Rupture pressure is at 500+ psi. Elongation at 698% is acceptable. It has a strength value of 13,600 psi compared to PEEK 15,300 - 16,200 psi. Nylon 12: This material had a average rupture of 291 psi which is unacceptable. See spreadsheets for additional information EVAL: This materials has an unacceptable rupture pressure. When material came in contact with water at 37c it became very supple( noodle-like). Because of these results this material is found to be unacceptable. See spreadsheets for additional information PAEK: There were 3-4 attempts to extrude tubing and because of difficulties no tubing was obtained. Recommendation: Continue PEEK development efforts for the Next Generation .014" O-T-W. Continue in-house development efforts along with procuring material from Accutech. All materials tested do not have the performance that is comparable to PEEK. With regard to PEEK improvements, the only improvement that I can foresee would be to increase the elongation properties to improve post processing conditions. Optimizing the PEEK extrusion will start in June 1994 with Steve Schaible completing a DOE for extrusion conditions. PAEK should be investigated at a later time. Miscellaneous: Material information for rupture data can be located in Eric William's lab notebook. For information regarding the mechanical properties see Ted Slater in the Materials Department. Additional information can be found in Larry Wasicek's lab notebook

Material Properties

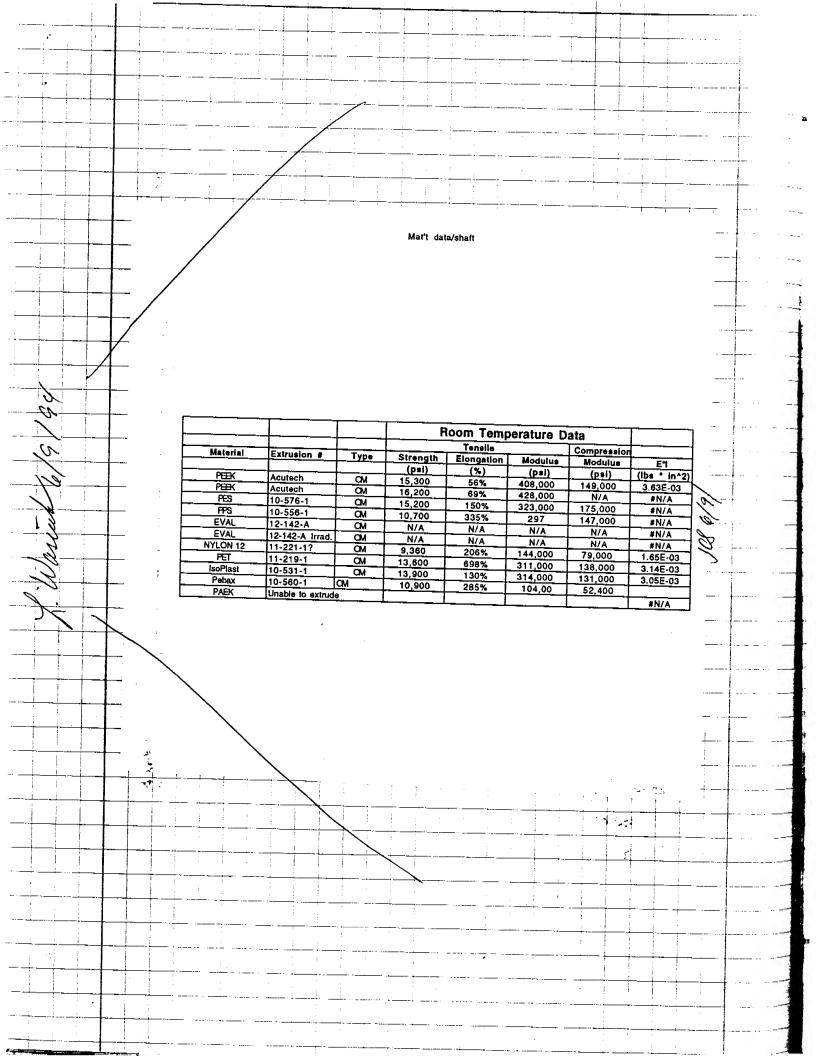
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Pebax	1147	NG		667	Z/A	280	N/A	N/A	N/A	From J. Lee
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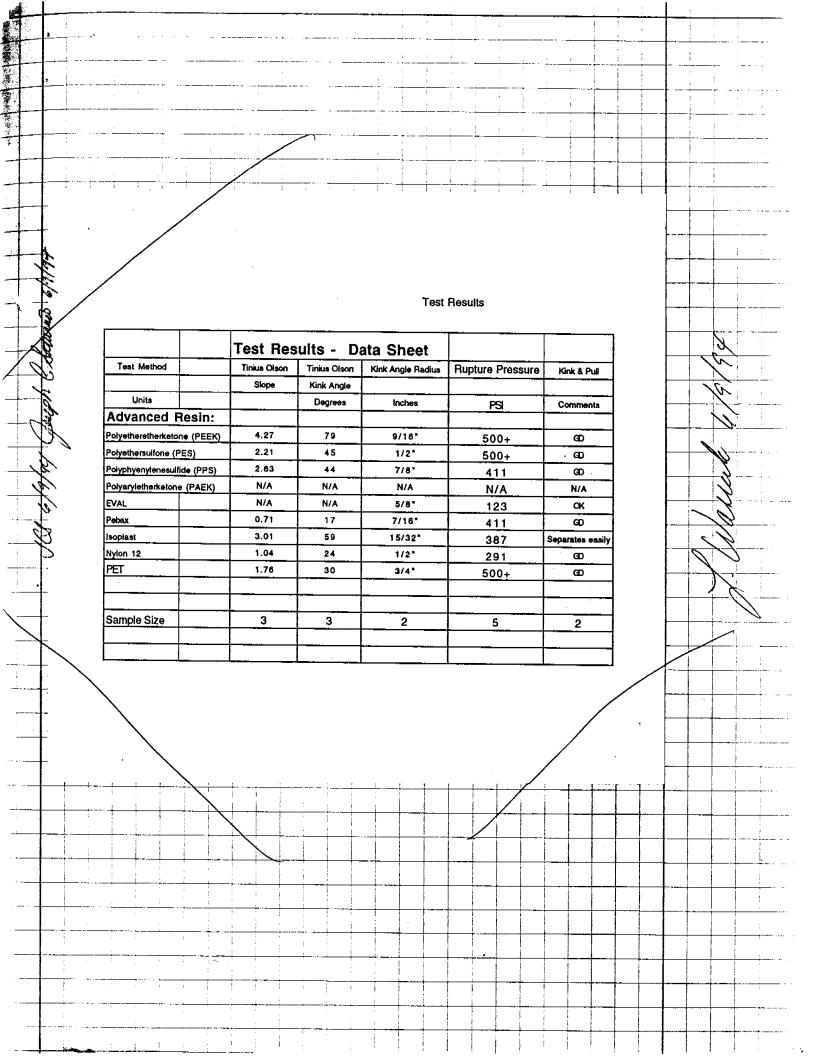
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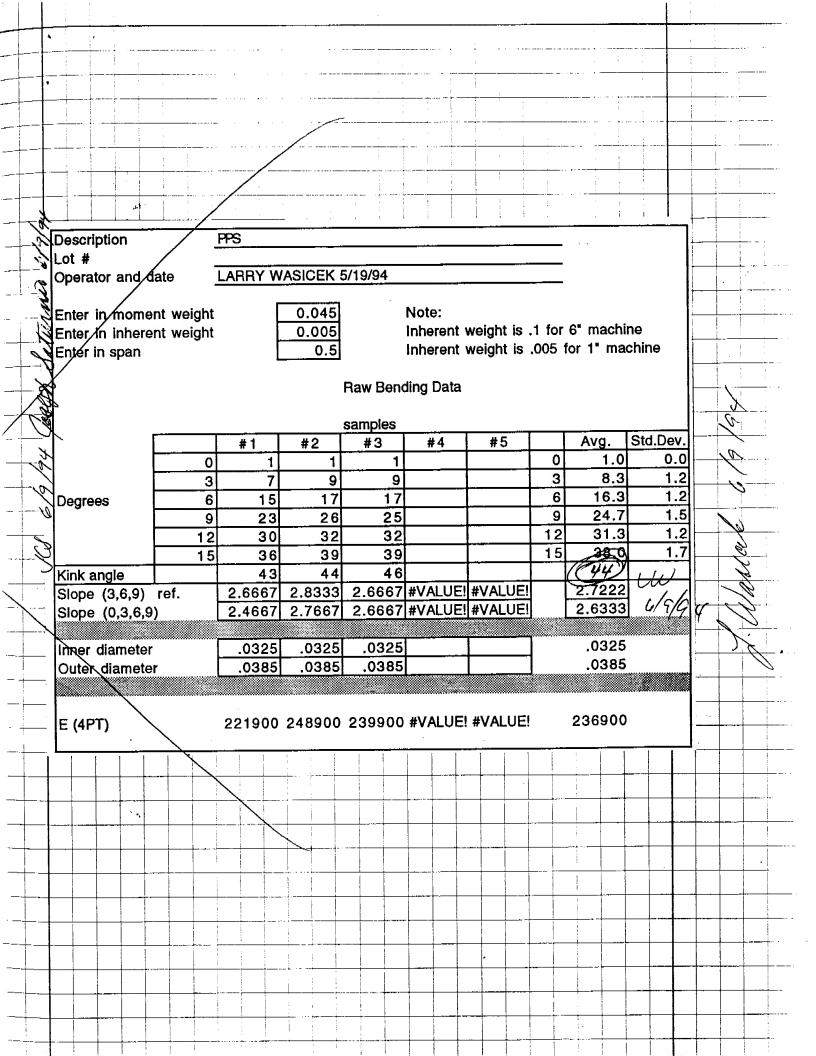
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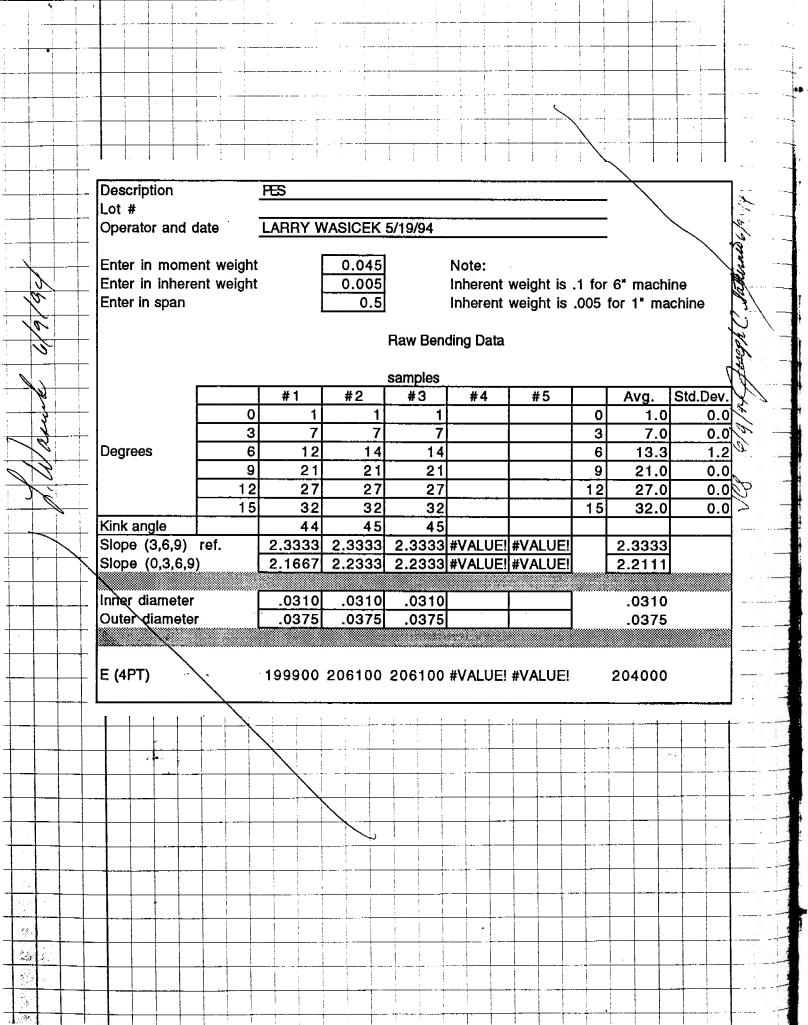
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